

Serial No.: 10/632,008
 Examiner: Sharon E. Kennedy
 Group Art Unit: 1615

STATUS OF CLAIMS

Claims 1-27 are presently pending in the application. Claims 24-27 were previously withdrawn from consideration pursuant to a restriction requirement. Thus, claims 1-23 are currently under examination. Applicant has amended claim 1. Claims 2 and 3 have been cancelled. Support for the amendment to claim 1 is found, *inter alia*, in claims 2 and 3 as originally filed. Applicant submits that no new matter has been added.

REMARKS

Rejection Under 35 U.S.C. §102(b)

Claims 1, 2, 4, 5, 6, 7, and 18 are rejected under 35 U.S.C. § 102(b) as being anticipated by Picha (U.S. Patent No. 5,342,628). In the Office Action, the Examiner takes the position that Picha discloses a drug diffusion polymer system for sustained release (abstract) comprising various polysiloxane polymers which may be used to form sustained release drug delivery systems or formulated as coatings on various medical instruments. The Examiner asserts that Picha discloses a polymeric matrix made of a copolymer of dimethylpolysiloxane and polymethylmethacrylate. The Examiner states that the Picha matrix expanded meets the claimed limitation for a "supplemental polymer."

Claims 8-17, 19, 21, 22, and 23 are rejected under 35 U.S.C. § 102(b) as being anticipated by Picha (U.S. Patent No. 5,342,628) or in the alternative as obvious over Picha. The Examiner states that claim 8 recites a very modest elongation at break for a medical device and silicone polymers typically have very high elongation break values. The Examiner takes the position that since the polymers claimed by applicant are identically described in Picha the claimed elongation at rate is inherent from the disclosure or it would be obvious to modify the Picha polymer to have a higher elongation at break depending on the use of the Picha device.

Claims 1 and 3 are rejected under 35 U.S.C. § 102(b) as being anticipated by Zaffaroni (U.S. Patent No. 3,896,819).

In response, Applicants respectfully traverse the rejections and their accompanying remarks. For a reference to anticipate a claim it must disclose each and every element of the claim. *See* MPEP 2131 and cases cited therein, *especially Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989) and *In re Marshall*, 578 F.2d 301, 304, 198 USPQ 344, 346 (Fed. Cir. 1978).

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Regarding the rejection under 102(b) over Picha, Applicants have hereby amended independent claim 1 (all other claims rejected with respect to Picha being dependent upon claim 1) to incorporate the limitations of dependent claim 3, which was not rejected under 102(b) with respect to Picha. As amended, claim 1 further requires that the polymeric release region is a barrier region disposed over a therapeutic-agent-containing region that comprises said therapeutic agent. Thus, Applicants state that the claims as amended are not anticipated by Picha and requests that the Examiner reconsider and withdraw the rejection with respect to Picha.

Regarding Zaffaroni, the Examiner rejected claims 1 and 3 as anticipated by Zaffaroni. The Examiner takes the position that Zaffaroni teaches that the wall of the delivery device may comprise siloxanes.

In response, Applicants respectfully traverse the rejection and states that the claims are not anticipated by Zaffaroni. Applicants have amended independent claim 1 to incorporate the claim limitations of dependent claim 2, which was not rejected under 102(b) with respect to Zaffaroni. Claim 3 has been cancelled. As amended, claim 1 further requires that the polymeric release region is a carrier region that comprises said therapeutic agent. Thus, Applicants state that the claims as amended are not anticipated by Zaffaroni and requests that the Examiner reconsider and withdraw the rejection with respect to Zaffaroni.

Rejection Under 35 U.S.C. §103(a)

Claim 20 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Picha.

In response, Applicant respectfully traverses the rejection and its accompanying remarks. Applicant asserts that the Examiner has not provided sufficient evidence to support a *prima facie* case of obviousness. The Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art. The Examiner can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. *In re Fritch*, 972 F.2d 1260, 1265, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992). An adequate showing of motivation to combine requires "evidence that 'a skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the

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manner claimed.” *Ecolchem, Inc. v. Southern Calif. Edison Co.*, 227 F.3d 1361, 1375, 56 USPQ2d 1065, 1076 (Fed. Cir. 2000).

Applicant states that for the reasons stated above with respect to the anticipatory rejection over Picha, Picha does not teach the claimed invention as stated in amended independent claim 1, upon which rejected claim 20 depends.

For at least these reasons, Applicants respectfully submit that claim 20 is patentable over the cited Picha reference.

CONCLUSION

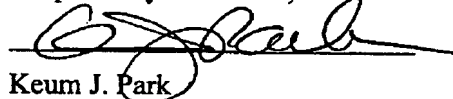
Applicants respectfully submit that all pending claims are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite the application at large, request is made that the Examiner telephone the undersigned attorney at (908) 518-7700, ext. 7 in order to resolve any outstanding issues.

FEES

The Office is authorized to charge any fees required to deposit account number 50-1047.

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Respectfully submitted,



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I hereby certify that this correspondence and any document referenced herein is being sent to the United States Patent and Trademark office via Facsimile to: 571-273-8300 on 5/31/07.

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